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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,906	DIECKMANN ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 7 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *18-24 and 28-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/02/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 2-17 and 25-27, and SEQ ID NO: 5 in the reply filed on 04/15/2005 is acknowledged. Claims 18-24 and 28-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Applicants traverse of the restriction requirement is acknowledged but not found persuasive. Applicants ask that Groups I and II be examined together because "...in view of the length of the claimed oligonucleotides, it is believed that it is unlikely that the probe would be successful in in situ hybridization [because] [g]enerally, a probe length of at least 50 base pairs is required for in situ hybridization."

The instant claims are drawn to a compound 8-50 nucleobases in length and Applicants have not provided any evidence that the claimed compound, 8-50 nucleobases in length, cannot be used as a probe in *in situ* hybridization. Further, as stated in the Office Action filed 03/15/2005, restriction is proper between the product and process of use because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other and it would be a search burden to search these inventions in a single application.

Applicants further state that "...examination of all the sequences in claims 7 and 8 fails to place an undue burden on the Patent Office [because] [an] [e]xaminer must examine all members of the Markush group if the members are sufficiently a small number or so closely related that a search and examination of the entire claim can be made without a serious search burden."

As stated in the Office Action filed 03/15/2005, although the oligonucleotide sequences claimed each target and modulate expression of MMP-12, the instant oligonucleotide sequences are considered to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each oligonucleotide sequence has a unique nucleotide sequence, each oligonucleotide sequence targets a different and specific region of MMP-12 nucleic acid, and each oligonucleotide, upon binding to MMP-12 nucleic acid, inhibits the expression of the gene and to varying degrees (per specification, page 26 lines 18-22). As such the Markush/genus of oligonucleotide sequences in Claims 7 and 8 are not considered to constitute a proper genus, and are therefore subject to restriction.

Therefore, the restriction is deemed proper and made FINAL.

Status of the Application

Claims 1-17 and 25-27 are pending and currently under examination. Claims 18-24 and 28-33 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites, "...the oligonucleotide is RNAi...". It is unclear what is meant by this phrase because an oligonucleotide cannot *be* RNAi. RNAi is disclosed in the specification as "RNA interference." RNA interference is a process wherein "...dsRNAs can provoke gene silencing." (See page 10, lines 24-26). Thus, an oligonucleotide cannot be a process.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 recite the limitation "wherein the target sequence". There is insufficient antecedent basis for this limitation in the claim.

Claims 5 and 6 recite the limitation "wherein the oligonucleotide". There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recite the limitation "wherein in that said oligonucleotide". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 9-15 and 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by An et al. (US 2003/0157110).

The instant claims are drawn to a compound 8-50 nucleobases in length targeted to a gene encoding metalloproteinase 12 (MMP-12) that specifically hybridizes to and inhibits the translation of MMP-12 protein. The claims further recite the compound is chemically modified wherein the substitution is on nucleic acid backbone or a nucleotide from the 3" or 5" ends or both (claims 9-11), wherein the compound is composed of DNA or RNA or an analogue or mimic of DNA or RNA (claims 12-13), wherein the compound comprises one modified sugar moiety (claims 14-15), wherein the compound is a composition that comprises a pharmaceutically acceptable carrier (claims 16-17) and further wherein a recombinant nucleotide sequence comprises the compound (claims 25-27).

An et al. disclose a compound targeted to MMP-12 that are 5-50 nucleobases in length (paragraph 0182) and further disclose the compound can be modified at the base or sugar moiety wherein the modifications can be MOE or phosphorothioate or PNAs (see paragraph 0184-0187). An et al. disclose a compound can be produced in an expression vector (see paragraph 0182).

Thus, An et al. anticipate claims 1-6, 9-15 and 25-27 of the instant application.

Claim Rejections - 35 USC § 102 or 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) as being anticipated by or obvious over McSwiggen *et al.* (U.S. Patent No: 5,639,532).

The instant claims are drawn to a compound 8 to 50 nucleobases in length targeted the nucleic acid sequence (SEQ ID NO: 1) encoding MMP-12, wherein the compound specifically hybridizes with and inhibits translation of MMP-12.

McSwiggen *et al.* teach a compound, 14 nucleobases in length (SEQ ID NO: 599) targeted to a nucleic acid molecule (SEQ ID NO: 1) encoding MMP-12, (see specification, column 229). The nucleic acid sequence taught by McSwiggen *et al.* meets the structural limitation of claims 1-2 of the instant application and would be expected to specifically hybridize to a nucleic acid encoding MMP-12. Furthermore, since the prior art antisense compound meets all the structural limitations of the claims, the prior art antisense would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example,

MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Thus, the instant claims 1-2 are anticipated or obvious over McSwiggen *et al.*

Claims 1-2 are rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) as being anticipated by or obvious over Naik *et al.* (Patent No: 6,242,587).

The instant claims are drawn to a compound 8 to 50 nucleobases in length targeted the nucleic acid sequence (SEQ ID NO: 1) encoding MMP-12, wherein the compound specifically hybridizes with and inhibits translation of MMP-12.

Naik *et al.* teach a compound, 18 nucleobases in length (SEQ ID NO: 10) targeted to a nucleic acid molecule (SEQ ID NO: 1) encoding MMP-12, (see specification, column 21). The specification states "...a sequence antisense compound need not be 100% complementary to that of its target nucleic acid to be specifically hybridizable...". Therefore, the nucleic acid sequence taught by Naik *et al.* meets the structural limitation of claims 1-2 of the instant application and would be expected to specifically hybridize to a nucleic acid encoding MMP-12. Furthermore, since the prior art antisense compound meets all the structural limitations of the claims, the prior

art antisense would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Thus, the instant claims 1-2 are anticipated or is obvious over Naik *et al.*

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) as being anticipated by or obvious over Kretschmer *et al.* (Patent No: 5, 583,035).

The instant claims are drawn to a compound 8 to 50 nucleobases in length targeted the nucleic acid sequence (SEQ ID NO: 2) encoding MMP-12, wherein the compound specifically hybridizes with and inhibits translation of MMP-12.

Kretschmer *et al.* teach a compound, 18 nucleobases in length (SEQ ID NO: 3) targeted to a nucleic acid molecule (SEQ ID NO: 2) encoding MMP-12, (see specification, column 21). The specification states "...a sequence antisense compound need not be 100% complementary to that of its target nucleic acid to be specifically hybridizable...". Therefore, the nucleic acid sequence taught by Kretschmer *et al.* meets the structural limitation of claims 1 and 3 of the

instant application and would be expected to specifically hybridize to a nucleic acid encoding MMP-12. Furthermore, since the prior art antisense compound meets all the structural limitations of the claims, the prior art antisense would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Thus, the instant claims 1 and 3 are anticipated or is obvious over Kretschmer *et al.*

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) as being anticipated by or obvious over Stinchcomb *et al.* (Patent No: 5,817,796).

The instant claims are drawn to a compound 8 to 50 nucleobases in length targeted the nucleic acid sequence (SEQ ID NO: 2) encoding MMP-12, wherein the compound specifically hybridizes with and inhibits translation of MMP-12.

Stinchcomb *et al.* teach a compound, 18 nucleobases in length (SEQ ID NO: 1000) targeted to a nucleic acid molecule (SEQ ID NO: 2) encoding MMP-12, (see specification,

column 399). The specification states "...a sequence antisense compound need not be 100% complementary to that of its target nucleic acid to be specifically hybridizable...". Therefore, the nucleic acid sequence taught by Stinchcomb *et al.* meets the structural limitation of claims 1 and 3 of the instant application and would be expected to specifically hybridize to a nucleic acid encoding MMP-12. Furthermore, since the prior art antisense compound meets all the structural limitations of the claims, the prior art antisense would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Thus, the instant claims 1 and 3 are anticipated or is obvious over Stinchcomb *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over An et al. (US 2003/0157110) in view of Bennett et al. (U.S. Patent No. 5,998,148) and in further view of Baracchini et al. (U.S. Patent No. 5,801,154).

The instant claims are drawn to a compound 8-50 nucleobases in length targeted to a gene encoding metalloproteinase 12 (MMP-12) that specifically hybridizes to and inhibits the translation of MMP-12 protein. The claims further recite the compound is chemically modified wherein the substitution is on nucleic acid backbone or a nucleotide from the 3" or 5" ends or both (claims 9-11), wherein the compound is composed of DNA or RNA or an analogue or mimic of DNA or RNA (claims 12-13), wherein the compound comprises one modified sugar moiety (claims 14-15), wherein the compound is a composition that comprises a pharmaceutically acceptable carrier (claims 16-17) and further wherein a recombinant nucleotide sequence comprises a the compound (claims 25-27).

An et al. disclose a compound targeted to MMP-12 that is 5-50 nucleobases in length (paragraph 0182) and further disclose the compound can be modified at the base or sugar moiety wherein the modifications can be MOE or phosphorothioate or PNAs (see paragraph 0184-0187). An et al. teach that a compound can be produced in an expression vector (see paragraph 0182). An et al. does not teach a pharmaceutically acceptable carrier or colloidal dispersion system.

Baracchini *et al.* teach that antisense oligonucleotides can be used for research purposes, and also teach that preferred antisense oligonucleotides are modified in their sugar, backbone linkage and nucleobase composition (col. 6). Baracchini teaches that such modifications are

desirable in antisense oligos because these modifications have desirable properties such as enhanced cellular uptake, enhanced affinity for nucleic acid targets and increased stability in the presence of nucleases. Baracchini et al provide specific embodiments of such modifications at columns 6-8 and in Example 1. These specific examples taught by Baracchini et al include the presently claimed phosphorothioate linkages, 2'-O-methoxyethyl sugars, 5-methylcytosine and chimeric oligonucleotides. Tables 1-4 show the successful design and use of modified oligonucleotides in cells in culture. Table 1 exemplifies the successful practice of general antisense design taught at columns 8-10. Column 4 teaches various carriers for antisense delivery. Baracchini *et al.* also teaches at column 8 that antisense oligonucleotides are preferably 8 to 30 nucleotides and that it is more preferable to make antisense oligonucleotides that are 12 to 25 nucleotides in length. Baracchini is considered to comprise a detailed blueprint for how to make and use inhibitory antisense oligos to target any known gene.

The teachings of Bennett *et al.* are considered to parallel those of Baracchini *et al.* Bennett *et al.* teaches general antisense targeting guidelines at columns 3-4. Bennett *et al.* also teaches targeting coding regions of a desire target, which encompass nucleotides 96-523 of the instant claims. Bennett teaches, in column 5, for example, that antisense compounds are commonly used as research reagents and diagnostics. Column 5 indicates that antisense oligonucleotides 8-30 nucleotides in length are particularly preferred. Columns 6-7 teach that preferred antisense oligonucleotides contain modified internucleoside linkages including phosphorothioate linkages, among others. Columns 7-8 teach that preferred antisense oligonucleotides comprise modified sugar moieties including 2'-O-methoxyethyl. Bennett *et al.* also teach one of ordinary skill to modify nucleobases in antisense oligonucleotides, including

the teaching of 5-methylcytosine (col. 8-9), and also to use chimeric antisense oligonucleotides (col. 9-10). Bennett *et al.* teach that the above modifications are known in the art to provide beneficial attributes to antisense oligonucleotides such as increased hybridization and nuclease protection, for example. Table 1 teaches the successful targeting of those regions taught in columns 3-4 with chimeric phosphorothioate oligonucleotides having 2'-MOE (a 2'-O-methoxyethyl modification). Thus, Bennett *et al.* is also considered to comprise a detailed blueprint for how to make and use inhibitory antisense oligos to target any known gene.

It would have been obvious to one of ordinary skill in the art to incorporate modifications as taught by Baracchini *et al.* and Bennett *et al.* into said antisense compounds, as taught by An et al.

One would have been motivated to create such compounds because An et al. expressly teach antisense compounds that target and hybridize to a nucleic acid encoding MMP-12. One would have been motivated to modify said antisense compounds as taught by Baracchini *et al.* and Bennett *et al.*, because both teach that such modifications increase an antisense compound's cellular uptake, target affinity and resistance to degradation. Further, one would have been motivated to create and modify such compounds because Bennett *et al.* teach antisense compounds that specifically target a desired gene can be used to elucidate the function of the particular gene.

Finally, one would have a reasonable expectation of success because Baracchini *et al.* and Bennett *et al.* both teach making modified antisense compounds targeted to distinct regions of a target gene, the steps of which are routine to one of ordinary skill in the art.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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Kimberly Chong
Examiner
Art Unit 1635